

REMARKS

Claims 1, 6-22, 27, and 33-35 are pending in the present application. As an initial matter, Applicant requests withdrawal of the finality of the previous Office Action, as the issuance of a final Office Action by the Examiner was improper. As stated by MPEP 706.07(a):

second or any subsequent actions on the merits shall be final, except where the examiner introduces a new grounds of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(a) with the fee set forth in 37 CFR 1.17(q).

In this case, the Examiner has introduced a new ground of rejection. Specifically, claims 1, 6-7, 27, and 33-35 are now being rejected as being allegedly rendered obvious by U.S. Patent No. 6,6630,296 to Ruggieri in view of U.S. Patent No. 6,488,872 to Beebe. In the previous Office Action of 7/14/04, such a rejection was not presented (the Beebe reference was not cited against the present application) and therefore the present rejection is a new ground of rejection.

The Examiner stated that Applicant's amendment necessitated this new ground of rejection. However, this is wholly incorrect as the Applicants' amendments of 11/10/04, only re-phrased the previously claimed gaskets as a polymer gel mask having cavities. There was no new subject matter added by way of these amendments that would in anyway necessitate a new ground of rejection. In fact, it seems clear that the reason for these new rejections had nothing to do with Applicant's amendments of 11/10/04, but rather due to the fact that in the previous Office Action, the Examiner rejected these claims in view of a reference (i.e. WO 01/07164 to Mitsuhashi) that did not even qualify as prior art. Therefore, if the claims were to be rejected again, new references had to be uncovered and cited against the Applicant in a subsequent Office Action. Such a subsequent rejection was in no way due to Applicants' amendments of 11/10/04. For these reasons, the Applicant requests withdrawal of the finality of the Office Action.

The specification stands objected to under than 35 U.S.C. 132 for allegedly introducing new matter into the specification. Claims 1, 5-7, 27, and 33-35 stand rejected under 35 U.S.C. 112 for allegedly lacking written description. Claims 1, 6-7, 27 and 33-35 stand rejected under 35 U.S.C. 103(a) for being allegedly rendered obvious by U.S.

Patent No. 6,630,296 to Ruggieri ("Ruggieri") in view of U.S. Patent No. 6,488,872 to Beebe ("Beebe").

Objection of Specification Under 35 U.S.C. 132

The specification stands objected to under than 35 U.S.C. 132 for allegedly introducing new matter into the disclosure. Specifically, the Examiner objects to the express incorporation of parts of U.S. Application No. 09/705,187 (the '187 application), which was incorporated by reference into the present application. The Examiner states that the present application does not make reference to the '187 application as "essential material necessary to support the claims." Applicant is aware of no requirement that Applicant must state in the specification that disclosure incorporated by reference is essential material to the claims. Notwithstanding, the Examiner apparently does not believe that the '187 application was properly incorporated by reference. Applicants respectfully submit that the '187 application was indeed properly incorporated by reference.

The present specification describes a gasket that may be placed on a surface at any time during the process of making arrays and may be removed if separation of groups or arrays is no longer necessary. The specification then refers to U.S. Patent Application No. 09/705,187 by serial number and title. See page 9, paragraph 21. The present specification also states that "all publications, patents, and patent applications referenced herein are hereby incorporated by reference to the same extent as if each was individually so incorporated." See page 59, paragraph 126. As such, Applicant is unclear as to what else the Examiner requires in order for the '187 application to be properly incorporated by reference. Because Applicant has identified the '187 application by serial number and title and has expressly stated that all patent applications are incorporated by reference, Applicant has properly incorporated the '187 application by reference.

As such, the express inclusion of subject matter from the '187 application is not new matter. MPEP 2163.7(b) states that "replacing the identified material incorporated by reference with the actual text is not new matter." Applicant also submits a declaration herewith stating that the amendatory material consists of the same material incorporated

by reference in the present application. Applicants thereby request withdrawal of this rejection.

Rejection of Claim under 35 U.S.C. 112

Applicant submits that claims 1, 5-7, 27, and 33-35 are supported, *inter alia*, by the amended specification submitted in the previous Response. The Examiner states that the specification does not provide a description of a method by which a polymer gel contact mask with cavities has a size and orientation of wells of a 96 well, 384 well and other recited multi-well format. The specification as amended in the Amendment of November 10, 2004, states that "such a [polymer gel] mask has a plurality of holes through it. Each of the holes, together with the portion of the substrate surface which it overlies, forms a cavity. Biological and chemical materials can be deposited into each of the cavities individually." The claims have also been amended to clarify that the tyrosine kinases are immobilized in areas having the size and orientation of wells of a 96-well, 384 well, 1536-well or 3456 well microwell plate." Support for this amendment can be found in paragraph 56, lines 4-5 of the original specification.

The Examiner also states that the as-filed instant specification presents a different concept and provides a description of a gasket and does not recite the use of gasket or polymer gel mask in the alternative. The present application refers to a gasket and then references an application entitled "Polymer Gel Contact Masks and Methods and Molds for Making Same." Therefore, the terms gasket and polymer gel mask are both used in the present specification. Further, their function is similar, as recited by the amended specification. Specifically, the original specification states that "in certain embodiments, such as where a surface without wells is used, binding islands may be formed or biomolecules may be immobilized on a surface and a gasket having holes spatially arranged so that they correspond to the islands or biomolecules may be placed on the surface." See paragraph 21. The amended specification states that "a contact mask is placed over a substrate to conceal a portion of the substrate and leave a plurality of discontinuous portions of the substrate exposed. Such a mask has a plurality of holes through it. Each of the holes, together with the portion of the substrate surface which it

overlies, forms a cavity. Biological and chemical materials can be deposited into each of the cavities individually.” As such, the gaskets and polymer gel masks are shown to have the exact same function and since both are referenced in the originally filed specification, it is appropriate to refer to them in the alternative in the amended specification.

The Examiner also states that the specification does not describe how the polymer gel contact mask is used such that the method of detecting modification of a target member of a biochemical pathway is obtained. The claims recite that the polymer gel contact mask having holes is placed on a substrate and tyrosine kinases are immobilized in the cavities (step a and b of the claims). Such steps are clearly supported by the amended specification which states that “biological and chemical materials can be deposited into each of the cavities individually.” Such a polymer gel mask allows the creation of discrete arrays of biomolecules as explained by the specification in paragraph 21 and 22. Steps c-d are then described, *inter alia*, in paragraphs 33, 34, 38 and 39 of the specification. Therefore, the specification very clearly describes the role of the polymer gel contact mask in the detection methods recited in the present claims.

Rejection of Claims Under 35 U.S.C. 103(a)

Claims 1, 6-7, 27, and 33-35 stand rejected under 35 U.S.C. 103(a) as being rendered obvious by U.S. Patent No. 6,630,296 to Ruggieri (“Ruggieri”) in view of U.S. Patent No. 6,488,872 to Beebe (“Beebe”). Applicants traverse this rejection as a *prima facie* case of obviousness has not been established.

Even if there were motivation to combine Ruggieri with Beebe, which Applicant is in no way conceding, the combined teachings of Ruggieri and Beebe still do not teach or suggest each and every element of the claims. Namely, neither reference alone nor in combination discloses a “polymer gel contact mask having holes” as recited in the present claims.

With respect to Ruggieri, the Examiner acknowledges that Ruggieri does not teach or suggest a polymer gel contact mask. With respect to Beebe, although Beebe describes a polymer gel, it does not describe a “polymer gel contact mask having holes,” as recited by the present claims. Specifically, Beebe describes a polymerizable mixture

that forms a polymer gel in a channel upon application of a polymerization trigger. The Examiner seems to be asserting that because Beebe describes masking regions in the channel that are to be free of the polymer gel from the polymerization trigger, Beebe describes a “polymer gel contact mask” as recited by the present claims. However, the polymer gel described in Beebe is not a mask itself which covers certain regions of the channel and leaves other regions exposed, as does the polymer gel contact mask recited in the present claims. Rather, Beebe describes applying a mask over the channel to cover regions of the channel in which the polymer gel is not to be formed (the composition or material of the mask applied over the channel is not disclosed). Therefore, the polymer gel described in Beebe is not a “polymer gel contact mask having holes” that is applied to a substrate to form cavities in which tyrosine kinases can be immobilized, as required by the present claims.

Further, the teaching of such a polymer gel contact mask in Beebe does not make sense given the purpose of the polymer gel in Beebe. As shown in **Fig. 1A** of Beebe, a hydrogel 102 is placed in a microchannel 104 of a detection device 100. The hydrogel contracts upon exposure to an analyte of interest, thereby allowing component A in microchannel 108 to flow to a chamber 106 and mix with a component B and produce a detectable change, for example, a color change in chamber 106. The hydrogel thereby acts as a sensor to sense the presence of the analyte of interest. If the hydrogel 102 of Beebe had holes in it as recited by the polymer gel contact mask of the present claims, then component A in microchannel 108 could pass through the holes of the hydrogel 102 to chamber 106 without the hydrogel necessarily contracting in response to the analyte of interest. As such, component A would mix with component B and produce a false positive color change. Such a result would undermine the very propose of the detection device described in Beebe. Therefore, Beebe does not describe a polymer gel contact mask having holes as asserted by the Examiner. Rather, Beebe only describes a hydrogel, and nothing more. For at least these reasons Applicant submits that the present claims are not rendered obvious by Ruggieri in view of Beebe and Applicant requests withdrawal of this rejection.

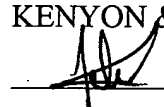
CONCLUSION

It is respectfully submitted that the present application is now in condition for , allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

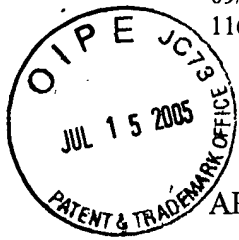
Respectfully submitted,
KENYON & KENYON

Dated: June 14, 2005


By: Zeba Ali
(Reg. No. 51,392)

1500 K Street, N.W.
Suite 700
Washington, D.C. 20005
Tel: (202) 220-4200
Fax: (202) 220-4201
572314

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: David DUFFY
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EXAMINER: T. Wessendorf
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF ZEBALI

I hereby declare that the amendatory material added to the above-referenced application in the amendment of 11/10/04 consists of the same material from U.S. Patent Application No. 09/705,187 entitled "Polymer Gel Contact Masks and Methods And Molds for Making Same."

The undersigned declares that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title '8 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: June 14 2005

Zeba Ali (Reg. No. 51,392)